Table 1

Event	In-hospital		Discharge — 1 month	
	Total	Ranking	Total	Ranking
Death	0	0	0	0
Q-AMI	0	0	1 (0.6%)	1
non-Q AMI	4 (2.5%)	4	0	0
CABG	0	0	1 (0.6%)	1
rePTCA	1 (0.6%)	0	2 (1.3%)	2
SAT	1 (0.6%)	0	0	0

stent thrombosis (SAT) and cardiac events were assessed in 160 pts. All pts received a single Palmaz-Schatz stent because of stable angina and a de novo coronary lesion. The protocol outlines that pts meeting the IVUS criteria of optimal stent expansion only receive ASA ≥ 100 mg, while those not meeting the criteria receive ASA, oral and iv anticoagulation after stenting. 83% of the pts received ASA (of whom 17% should have been treated with anticoagulants — protocol violation) and 17% received systemic anticoagulation. A total count of events and ranking according to the worst category analysis is shown in Table 1.

This multicentric study confirms that stents can indeed be safely implanted without the institution of systemic anticoagulation.

9:45

731-6 Integrelin for Emergency Coronary Artery Stenting

James P. Zidar, Kevin R. Kruse, Mark C. Thel, Dean Kereiakes, Joseph B. Muhlestein, Charles J. Davidson, Paul S. Teirstein, Alan Tenaglia, Steven J. Yakubov, Jeffrey J. Popma, Jean-Francois Tanguay, Michael M. Kitt, Todd J. Lorenz, James E. Tcheng, A. Michael Lincoff, Robert M. Califf, Eric J. Topol for the IMPACT II Investigators. *Duke University, Durham, NC*

To assess the potential benefit of GP IIb/IIIa inhibitors with coronary stenting, we studied 160 patients who required stents for true/threatened closure in the IMPACT II trial. In this trial of 4010 patients, no stents were placed electively by protocol design. A composite end point of death, MI, urgent repeat intervention or CABG was compared between the stent patients in the placebo arm vs. pts randomized to one of two Integrelin doses. Baseline characteristics were similar between the stent and non-stented groups. Enrollment status was characterized as high risk in 45% of patients in the stent group vs 41% in the non-stent group. Most (87%) stent patients received a Cook stent and were discharged on warfarin.

Endpoints at 30 days:	Integrelin (n = 101)	Placebo (n = 59)	p
Composite endpoint	31%	49%	0.021
MI	16%	32%	0.017
Urgent CABG	7%	8%	0.723
Urgent repeat intervention	6%	8%	0.546
Death	2%	1.7%	0.897
Major bleeding complication	21%	21%	0.956

Conclusions: The high event rates in both groups reflect the "true ballout" indication for stenting. Integrelin improves 30 day clinical outcome by reducing the risk of MI in patients requiring stents after failed PTCA, without an increase in bleeding. This suggests the importance of GP IIb/IIIa inhibition in coronary stenting.

732 Angioplasty and Restenosis: Role of Stents

Tuesday, March 26, 1996, 8:30 a.m.–10:00 a.m.
Orange County Convention Center, Room 314

8:30

732-1 Is There Need for Intravascular Ultrasound After High-Pressure Dilatations of Palmaz-Schatz Stents

Kathleen M. Allen, Cenap Undemir, Alexander Shaknovich, Jeffrey Moses, Janet Strain, Edward Kreps. *Lenox Hill Hospital, New York, NY*

Use of intravascular ultrasound (IVUS) in conjunction with angiographic assessment of Palmaz-Schatz stents (PSSs) provided the rationale for routine post-deployment high pressure dilatation (HPD) of PSSs. To address the question of whether routine HPD obviates the need for IVUS, we reviewed IVUS and quantitative angiographic (QCA) data in 91 pts with 96 lesions. HPD was performed in all pts (mean pressure 16.7 ± 1.6 ATM; range 14–20 ATM) with 1–1.1 balloon: artery ratio. Further improvements were necessary in 45/96 vessels after post-HPD IVUS secondary to suboptimal stent geometry (32), protruding tissue (5), and dissection/additional stenoses (8). 8 vessels required additional PSSs and 37 further HPDs (17 with the same and 20 with a larger balloon). IVUS (n = 45) and QCA (n = 30) were repeated after each HPD.

	Post HPD	Final	p value
QCA MLD (mm)	2.66 ± 0.54	2.92 ± 0.50	0.055
QCA stenosis %	5.95 ± 8.86	−1.82 ± 9.98	0.0007
IVUS MLD (mm)	2.81 ± 0.41	3.10 ± 0.39	0.001
IVUS stenosis %	19.6 ± 9.2	9.85 ± 12.2	0.0002
CSA (mm2)	7.5 ± 1.89	8.97 ± 2.03	0.001
Symmetry	0.88 ± 0.07	0.90 ± 0.062	0.21

Conclusions: In nearly half of PSSs, IVUS following HPD identified suboptimal results which were improved with further intervention. A prospective randomized trial will be necessary to verify if this strategy alters clinical outcome.

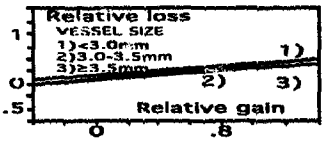
8:45

732-2 Influence of Vessel Size on the Late Restenotic Process After Successful Stent Implantation

Naoya Hamasaki, Hideyuki Nosaka, Takeshi Kimura, Hiroyoshi Yokoi, Takashi Tamura, Yoshihiro Sawada, Masakiyo Nobuyoshi. *Kitakyushu, Kokura Memorial Hospital, Japan*

The purpose of the present study was to investigate the influence of vessel size on late angiographic outcome after successful single stent placement. The study population comprised 547 consecutive lesions implanted native arteries [Palmatz-Schatz 436, Gianturco-Roubin 50, Cordis, 61] and satisfactoric angiographic analysis before and after stenting and at 3 or 6 months follow-up (FUP) from a single center (Feb. 1990–Feb. 1995).

Vessel size	< 3.0 mm	3.0–3.5 mm	≥ 3.5 mm	
Acute gain	1.86 ± 0.67	2.05 ± 0.44	2.22 ± 0.55	P = 0.0001
Late loss	0.89 ± 0.67	0.87 ± 0.64	0.81 ± 0.65	P = 0.56
MLD FUP	1.76 ± 0.63	2.02 ± 0.6	2.40 ± 0.63	P = 0.0001



Vessel size was found to be exert a significant positive influence on MLD at FUP and an equally negative effect on loss by multivariable analysis ($p < 0.001$). The relative gain/loss relationships within the lesion groups showed that it does not vary with vessel size. In conclusion, vessel size itself does not influence the restenosis process, which appears to be determined mainly by the degree of luminal increase achieved at stenting, regardless of the vessel size.

9:00

732-3 Distribution of Tissue Growth in Palmaz-Schatz Stents: Insights From a Serial Intravascular Ultrasound Study

Rainer Hoffman, Gary S. Mintz, Jeffrey J. Popma, Augusto D. Pichard, Lowell F. Satler, Kenneth M. Kent, Roxana Mehran, Martin B. Leon. *Washington Hospital Center, Washington, DC*

Previous studies have suggested that instent restenosis is (1) due to intimal hyperplasia and (2) occurs most frequently at the central articulation (CA) of Palmaz-Schatz stents. To understand this process, we compared serial [post-intervention and follow-up (F/U 5.4 ± 3.8 mos)] intravascular ultrasound studies in 104 stents implanted into 49 native and 39 SVG lesions. Lumen and stent areas (in mm^2) were measured; plaque (stent-lumen) area, late lumen loss (Δlumen area) and tissue growth (Δplaque area) were calculated for the edges, body, and CA of all stents:

	Edges	Body	CA	p (ANOVA)
Post stent area	10.1 ± 4.1	9.5 ± 3.6	9.6 ± 4.0	0.0005
F/U stent area	9.9 ± 4.1	9.6 ± 3.8	9.4 ± 3.8	0.01
Post lumen area	10.0 ± 4.0	9.5 ± 3.6	9.1 ± 3.9	<0.0001
F/U lumen area	7.1 ± 3.9	6.5 ± 3.6	6.0 ± 4.1	<0.0001
Post plaque area	0.0 ± 0.1	0.0 ± 0.0	0.5 ± 1.1	<0.0001
F/U plaque area	2.8 ± 2.0	3.0 ± 2.0	3.4 ± 2.6	<0.0001
Late lumen loss	2.9 ± 1.6	3.0 ± 2.0	3.1 ± 2.6	NS
Tissue growth	2.6 ± 1.9	2.9 ± 2.0	2.8 ± 2.5	NS

The lumen at the central articulation is smaller than at the body or edges of the stent because of a slightly smaller stent area and superimposed prolapse

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of tissue through the central articulation. Subsequent accumulation of neointimal tissue is uniformly distributed throughout the stent. *We conclude:* Serial intravascular ultrasound imaging shows that restenosis *at the CA* (compared to the edges or body) of Palmaz-Schatz stents is the result of a smaller initial lumen (smaller stent area and tissue prolapse) and not due to a propensity for increased neointimal tissue accumulation.

9:15

732-4 REstenosis STent (REST)-Study: Randomized Trial Comparing Stenting and Balloon Angioplasty for Treatment of Restenosis After Balloon Angioplasty

Raimund Erbel, Michael Haude, Hans W. Höpp, Carlos Macaya, Masakiyo Nobuyoshi, Peter Probst, Martin Sigmund, Hakan Emanuelsson, Bernd Heublein, Wolfgang Rutsch, Gunhild Herrmann, on behalf of the REST Study Group. *Dept. of Cardiology, University Essen, Germany*

The REST-Study is a multicenter randomized trial comparing the implantation of a single Palmaz-Schatz stent vs. balloon angioplasty (PTCA) in patients (pts) with restenosis in native coronary arteries. Pts enrolment (n = 400) was completed in May 1995. According to the protocol, an interim analysis acute and 6-month follow-up (FU) was performed on the first 123 pts. For quantitative coronary angiography, a CMS system (Medis, Netherlands) was used to assess pre, post intervention and at 6 month FU minimal luminal diameter.

	Stenting (n = 85)	PTCA (n = 87)
Reference diameter (mm)	3.01 ± 0.32	3.04 ± 0.26
MLD (mm) pre-intervention	1.25 ± 0.44	1.20 ± 0.35
MLD (mm) post-intervention	3.12 ± 0.43	2.33 ± 0.57
MLD (mm) at FU	2.14 ± 0.66	1.86 ± 0.56
Restenosis with reintervention	11.7%	37%
Acute thrombosis	1.2%	1.2%
Subacute thrombosis	3.5%	–
Emergency CABG	–	–
Bleeding	12.3%	4.6%
Death	–	–

The interim analysis of the REST-Study demonstrates (1) favorable results concerning acute and FU angiographic lumen diameter and (2) a reduced restenosis rate based on necessary reinterventions for stenting compared to PTCA.

9:30

732-5 Stenting in Chronic Coronary Occlusion (SICCO): A Multicenter, Randomized, Controlled Study

Per A. Simes, Svein Golf, Yngvar Myreng, Per Mo/stad, Per Albertsson, Håkan Emanuelsson, Magne Brekke, Arild Mangschau, Knut Endresen, John Kjekshus for the SICCO Study Group. *Feiring Heart Clinic, Feiring, Norway*

Angioplasty of chronic coronary occlusions (CCO) carries a high recurrence rate. We randomized 119 pts. (58 ± 11 years) after initial successful recanalization of CCO (duration ≥ 2 weeks, median 18 weeks, 33% TIMI-1 occlusions) to conventional PTCA or implantation of Palmaz-Schatz stent. The target vessel was LAD in 39%, LCX in 11%, and RCA in 50%. Coronary angiograms at baseline (after PTCA) and at 6 months follow-up examination were analyzed quantitatively.

Analysis of 91 pts. who had completed follow-up by Sep. 95 showed a restenosis (> 50%) rate of 73% in the PTCA group vs. 33% in the stent group (p = 0.0001). Reocclusion rate was 24% vs. 15% (p = 0.27). Angina class, minimal luminal diameter (MLD) and % diameter stenosis were significantly improved in the stent pts. There was one stent delivery failure. Major events (AMI, PTCA or ACB in occlusion territory) occurred in 14 pts. in the PTCA group and 8 pts. in the stent group.

	PTCA (n = 36)		Stent (n = 43)	
	baseline	6 months	baseline	6 months
Angina class (CCS)	2.80 ± 0.53	1.56 ± 1.1	2.72 ± 0.50	0.67 ± 0.95*
MLD (mm)	2.15 ± 0.63	1.11 ± 0.78	2.22 ± 0.51	1.78 ± 0.92*
Reference diameter	3.21 ± 0.53	3.34 ± 0.59	3.14 ± 0.45	3.29 ± 0.61
% Diameter stenosis	33 ± 12	67 ± 24	29 ± 13	46 ± 26*

(*p < 0.05 vs. PTCA). Follow-up will be completed by Dec. 95, and final results will be presented.

Conclusion: Primary stenting of chronic coronary occlusions improves the long term clinical and angiographic outcome.

9:45

732-6 Six Month Clinical and Angiographic Follow-Up of Stenting Without Anticoagulation: The Ticlopidine Aspirin Stent Evaluation (TASTE) Study

Jean-Marc Lablanche, Eugène P. Mc Fadden, Eric Van Belle, Nicolas Danchin, Gilles Grollier, Martial Hamon, Christophe Bauters, Michel E. Bertrand. *University of Lille, France*

Stent implantation without anticoagulation is now standard management in many countries. In a prospective multicenter French study, we have followed patients with stent implantation, managed with ticlopidine 500 mg and aspirin 200 mg daily, without oral anticoagulation. We report the angiographic follow-up in the first 105 patients who underwent successful stent implantation (TIMI grade 3 flow after stenting without in-hospital complication) and who were treated by protocol (ticlopidine continued for at least 1 month). Indications for stenting were failed angioplasty (n = 50), a suboptimal result (n = 41), or electively (n = 14).

During the 6 months after stenting 1 death, unrelated to stenting, occurred (leukaemia): 1 asymptomatic patient underwent bypass surgery (referring physician preference). Ticlopidine related neutropenia occurred in 4 patients (on day 30, 30, 60, 60): allergic reactions occurred in 4 patients (all before day 18): 1 digestive hemorrhage (at 1 month) and one gastritis (3 months) occurred.

At angiographic follow-up, restenosis (> 50% stenosis) was present in 38 stents (36%), including 3 occlusions (3.2%). Intrastent redilatation was performed in 19 (18%) patients; dilatation at non-stented segments in 11 (10.4%) patients.

In a population with a documented high risk of clinical complications stenting managed by antiplatelet therapy alone had an excellent clinical outcome. Further studies are required to determine the factors associated with restenosis in this population.

733 Diastolic Dysfunction: Mechanisms and Potential Treatment

Tuesday, March 26, 1996, 8:30 a.m.–10:00 a.m.
Orange County Convention Center, Room 230C

8:30

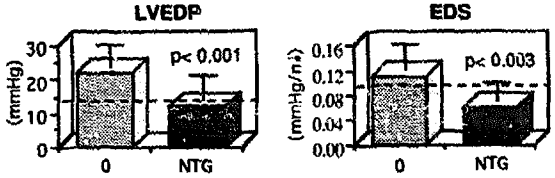
733-1 Improvement of Diastolic Dysfunction in Patients With Aortic Stenosis by Nitroglycerin

Christian Matter, Lazar Mandinov, Giuseppe Vassalli, Otto M. Hess. *Cardiology, University Hospital, Zurich, Switzerland*

Background: Diastolic dysfunction has been reported in the majority of patients with left ventricular (LV) pressure overload hypertrophy. Thus, the purpose of the present study was to evaluate the effect of nitroglycerin (NTG) on diastolic dysfunction in patients (pts) with severe aortic stenosis (AS).

Patients and Methods: A total of 20 pts (10 AS; 10 controls, C) were included in the present analysis. LV high-fidelity pressures and simultaneous LV volumes were determined at rest and after intracoronary administration of 150 μg NTG in AS pts. 7/10 AS pts had diastolic (LVEDP ≥ 14 mmHg) and 4/10 had systolic (EF < 57%) dysfunction.

Results: Ejection fraction (57 vs 59%; NS), LV end-diastolic volume, relaxation rate, early and late peak filling rate, LV end-systolic chamber stiffness as well as the constant of muscle stiffness (9 vs. 7; NS) remained unchanged after NTG. LV end-diastolic pressure (LVEDP), LV peak systolic pressure (LVSP: 204 vs. 190; p < 0.05) and LV end-diastolic chamber stiffness (EDS) decreased after NTG:



Conclusions. Diastolic dysfunction is present in 9/10 pts with severe AS and is improved in 7/10 by NTG, whereas systolic function remains unchanged. Thus, NTG exerts a beneficial effect on diastolic function in LV hypertrophy. This response is probably due to a vasodilatory (unloading) rather than a direct myocardial effect.

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